REMARKS/ARGUMENTS

Claim Objections

Claim 25 has been objected to because it recites "pegicol." In making this rejection the Examiner states that the term should be "peglicol." Applicants thank the Examiner for calling this typographical error to their attention. The term "pegicol" has been replaced with the term "peglicol" in paragraph [0131] of the Specification and in claim 25.

35 U.S.C. § 112, second paragraph

Claim 22 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because of the use of trademarks. Claim 22 is hereby cancelled. Withdrawal of this rejection is respectfully requested.

35 U.S.C. § 102

Claims 1-4, 14-21, 26-30 and 36-40 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Amin (US 4,902,683). For reasons set forth below Applicants respectfully disagree. In making this rejection the Examiner states that glyceryl mono stearate is an amphipathic oil and that carnauba wax or white wax are microcrystalline waxes. Applicants respectfully note that claim 1 is drawn not merely to an amphipathic oil, but to an amphipathic oil that is water dispersible and ethanol insoluble. While glyceryl monostearate is only slightly soluble in ethanol, it is soluble in hot water. Accordingly, glyceryl monostearate is not an amphipathic oil that is water dispersible and ethanol insoluble. Glyceryl monostearate is discussed in the present application. In paragraph [0081] it is shown that glyceryl monostearate ceftiofur hydrochloride formulations fell below 90% of the label potency after a storage period of less than 18 months at room temperature. In contrast, as set forth in paragraph [0084], compositions containing amphipathic oils that are water dispersible and ethanol insoluble maintained at least 90% of label potency for 24 months. Accordingly, Applicants respectfully submit that it is clear from the Specification that glyceryl monostearate is not an amphipathic oil usable in the present invention.

Microcrystalline waxes were well known at the time of the filing of the present application. This is shown in paragraph [0133] (page 17) of the Specification which notes that microcrystalline wax is defined both in the Handbook of Pharmaceutical Excipients, 3rd ed., or in the National Formulary, 19th ed. Both these references were available at the time of the filing. Applicants submit herewith a printout from Wikipedia, the free encyclopedia. This printout shows that microcrystalline waxes are hydrocarbon waxes which differ from paraffin wax in that the microcrystalline wax contains a higher percentage of branched hydrocarbons and cyclic hydrocarbons. Carnauba wax is a vegetable wax derived from the carnauba palm. As shown in the Wikipedia reference submitted herewith, carnauba wax is mainly esters of fatty acids, fatty alcohols, acids, and hydrocarbons. Clearly carnauba wax is not a microcrystalline wax.

White wax is a bleached beeswax as is shown in the attached printout of a portion of a Wikipedia reference. Beeswax is made up of fatty acid esters of long-chain aliphatic alcohols. Clearly white wax is not a microcrystalline wax. The Examiner notes that there are several other components cited in Amin which may optionally be used in the present invention. Applicants respectfully submit that Amin is missing the microcrystalline wax and the amphipathic oil which is water dispersible and ethanol insoluble. Since two of the major components of the carrier of the present invention are missing, the presence of other components does not change the conclusion that Amin does anticipate the present invention. Reconsideration and withdrawal of this rejection is respectfully requested.

The Examiner also notes that claims 2-4 recite an intended use for the composition and thus do not carry patentable weight. Applicants respectfully disagree. The Examiner has cited a section of the MPEP which provides examples of language that may raise a question as to the limiting effect of the language in the claim. Applicants respectfully note that the MPEP does not state that such language could never be limiting, but rather states that it may raise a question. In this case, the types of compositions used for mastitis differ in viscosity from those used for treatment of an infection in the ear. A composition useful for intramammary infusion is generally injected into the teat of the animal being treated. The composition must flow easily, and must be of low enough viscosity to be readily injectable through a relatively small cannula.

If such a composition were infused into the ear, it would flow out of the ear. A composition suitable for autic administration must have sufficient viscosity so that it will remain within the ear and not flow out. Applicants respectfully submit that in this case the limitations as to use function as limitations on viscosity, and thus do provide further limitation to claim 1. Reconsideration and withdrawal of this objection is respectfully requested.

35 U.S.C. § 103, Amin (US 4,902,683) in view of Nakajima (US 5,338,761)

Claims 23-25 and 31-35 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Amin (US 4,902,683) in view of Nakajima (US 5,338,761). Applicants respectfully note that the composition of Nakajima is an aqueous-based emulsion composition (see Abstract). The components cited by the Examiner are surfactants used in the emulsion (column 3, lines 11-34). Applicants respectfully submit that an aqueous emulsion does not read on the non-aqueous suspension of the present invention. There is no basis for combining the aqueous emulsion of Nakajima with the oil-based suspension of Amin. In fact, the combination of an oil-based suspension with an aqueous emulsion would be expected to lead to one of two results. If there is sufficient emulsifier present, then the excess oil could be incorporated into the emulsion. If there is insufficient emulsifier, one would expect to produce a two-phase composition. Neither case would lead to Applicants' invention. Furthermore, since Amin does not teach the microcrystalline wax, the combination of Nakajima and Amin is still lacking a key component of Applicants' invention.

Applicants respectfully note that the compositions of the present invention have low interfacial tension and therefore increased dispersibility (see paragraph 60). The compositions of the present invention also provide enhanced stability (see paragraphs 81 and 84). There is nothing in either Amin or Nakajima which suggests that these beneficial results could be obtained through the combination of Nakajima and Amin. Accordingly there is no reason that the person skilled in the art would have combined Nakajima and Amin with any expectation of producing a composition with better dispersibility and better stability. Reconsideration of and withdrawal of this rejection is respectfully requested.

35 U.S.C. § 112, first paragraph

Claims 1, 14, 21, 26 and 30-38 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In making this rejection the Examiner states that the claim is drawn to an amphipathic oil and further cites the definition of amphipathic oil contained in paragraph [0126]. The Examiner then states that "the genus of the amphipathic oil includes any and all known and unknown molecules that comprises of a polar and a non-polar regions." Applicants respectfully note that the claims are not drawn to an amphipathic oil, but rather to "an amphipathic oil that is water dispersible and ethanol insoluble." This claim is supported by paragraph [0127] which states "Amphipathic oils applicable to the current invention include all amphipathic oils that are water dispersible and ethanol insoluble." This is a rather narrow group of compounds. Furthermore, the person skilled in the art looking at the examples of amphipathic oils which are given, would readily understand what sort of oils would qualify. A simple test, that is, ethanol insolubility and water dispersibility, is provided. Water dispersibility may be determined by placing a quantity of an oil in a test tube and adding thereto a similar quantity of water. Upon shaking it will readily be apparent whether or not the oil is water dispersible. Similarly the same sort of test may be performed with an oil and ethanol. Accordingly, Applicants respectfully submit that the Specification provides a clear description of the types of amphipathic oils which are usable in the invention, and a clear method which may be used without undue experimentation to determine if the oil falls within the claims. Reconsideration and withdrawal of this rejection is respectfully requested.

The Examiner has stated that the chemical composition of Labrafil™ M-1944CS is unavailable. Applicants respectfully calls the Examiner's attention to paragraphs [0128] through [0131] which describe the various Labrafil™ oils as the product of the alcoholosis reaction of natural triglycerides with polyethylene glycols. Finally, in paragraph [0131] Labrafil™ M-1944CS is defined precisely as peglicol 5-oleate. Applicants respectfully submit that the composition of Labrafil™ M-1944CS is available. Reconsideration of and withdrawal of this rejection is respectfully requested.

The Examiner has alleged that the term "non-aqueous carrier" is not supported by the Specification. In making this rejection the Examiner states "Mere recitation of numerous compounds that belongs to several genera of compound classes does not satisfy the written description to a generic claim." Applicants respectfully submit that the non-aqueous carriers listed in the Specification belong to a small group of compounds. Thus all the named vegetable oils are glycerol esters of fatty acids. The oils which are formed from specific combinations of fatty acids are nonetheless glycerides; the synthetic oils may be propylene glycol esters of fatty acids. All of these molecules belong to the class of lipids. The two non-lipid substances in the Specification are polyethylene glycol and mineral oil. Applicants respectfully submit that the disclosure in the Specification fully supports the claim language which is "a pharmaceutically acceptable non-aqueous carrier..." Reconsideration of and withdrawal of this rejection is respectfully solicited.

The Examiner has alleged that the Applicants have not provided a proper definition of the term "microcrystalline wax." Applicants respectfully submit that microcrystalline wax is so well known that it is defined in the National Formulary and need not be defined further in a patent application. Accordingly, the Specification as filed fully supports the claims. Furthermore, the person skilled in the art is fully put in possession of the invention since he is given two readily available references which will explain the meaning of the term "microcrystalline wax." However, in order to expedite prosecution, Applicants are providing herewith a definition of the term "microcrystalline wax."

The Examiner has objected to claim 14 because it lists numerous compounds belonging to the genus cephalosporin. Applicants respectfully submit that this invention relates to a composition comprising a vehicle and an antibacterial substance dispersed therein. The benefits of the invention, that is, the higher dispersibility and the greater stability of the antibiotic substance arise from the formulation. The person skilled in the art would expect that any cephalosporin in this particular formulation would have both higher stability and higher dispersibility. The cases which the Examiner has cited do not relate to this particular issue. The Examiner has cited Regents of the University of California v. Eli Lilly & Co. for the proposition

that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." This application does not relate to the naming of a chemical genus. Instead it relates to a formulation which provides certain properties. These properties will be obtained no matter what type of antibiotic substance is suspended in the formulation. The Examiner has cited Fiers and In re Smythe that where there is unpredictability in performance of certain species or subcombinations the person skilled in the art will not have been placed in possession of a genus. There does not appear to be any uncertainty here. As set forth above, the dispersibility and the stabilization arise from the nature of the carrier, not from the nature of the antibiotic substance. Reconsideration of and withdrawal of this rejection is respectfully solicited.

If the Examiner believes that personal communications will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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John H. Engelmann

John H. Engelmann
Registration No. 28,075
Pfizer Inc.
7000 Portage Road
Kalamazoo, MI 49001
Tel. (269) 833-2532
Fax (269) 833-8897